Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Original): A method of collecting a bodily fluid sample from an incision in the skin comprising:

pressing against the skin a stimulator sleeve of a bodily fluid sampling device around the incision to express the bodily fluid sample; and

moving a capillary tube of the bodily fluid sampling device towards the incision by moving the capillary tube relative to the stimulator sleeve while the sleeve remains in contact with the skin.

2. (Original): The method of claim 1, further comprising forming the incision in the skin with a needle of the bodily fluid sampling device.

3. (Original): The method of claim 1, further comprising forming the incision with the bodily fluid sampling device before said moving.

4. (Original): The method of claim 3, further comprising drawing the bodily fluid from the incision into the capillary tube.

5. (Original): The method of claim 4, further comprising transferring the bodily fluid onto a test strip located at one end of the capillary tube.

6. (Original): The method of claim 5, further comprising analyzing the bodily fluid on the test strip.

7. (Original): The method of claim 1, further comprising drawing the bodily fluid from the incision into the capillary tube.

8. (Original): The method of claim 7, further comprising transferring the bodily fluid from the capillary tube onto a test strip.

9. (Original): The method of claim 8, further comprising analyzing the bodily fluid on the test strip.

10. (Original): A method of collecting a sample of bodily fluid from an incision in the skin, comprising:

pressing against the skin a stimulator sleeve of a bodily fluid sampling device around the incision to express at least a drop of the bodily fluid; and

moving a means for collecting the bodily fluid in the bodily fluid sampling device towards the drop by moving the means for collecting the bodily fluid relative to the stimulator sleeve while the sleeve remains in contact with the skin.

11. (Original): The method of claim 10, wherein:

the means for collecting the bodily fluid includes a capillary tube with an end; and

said moving includes extending the end of the capillary tube towards the drop.

12. (Original): The method of claim 10, wherein:

the bodily fluid sampling device includes an inner sleeve having a slot;

the stimulator sleeve is slidable relative to the inner sleeve;

the means for collecting the bodily fluid includes a test strip received in the slot of the inner sleeve; and

said moving includes sliding the inner sleeve relative to the stimulator sleeve to contact the test strip with the drop.

13. (Original): The method of claim 10, further comprising forming the incision with the bodily fluid sampling device before said moving.

14. (Previously Presented): A method, comprising:

placing a sampling device in contact with a non-digit body part;

creating an incision in the non-digit body part with the sampling device; and

testing body fluid on the surface of the non-digit body part from the incision with the sampling device while the sampling device remains in contact with the non-digit body part.

15. (Previously Presented): The method of claim 14, further comprising sampling the body fluid from the incision with the sampling device before said testing.

16. (Previously Presented): The method of claim 15, wherein said sampling the body fluid includes drawing fluid into a capillary in the sampling device via capillary action.

17. (Previously Presented): The method of claim 16, wherein said testing includes analyzing the body fluid with a test strip disposed along the capillary.

18. (Previously Presented): The method of claim 15, wherein said sampling includes:

moving a capillary from a first position where the capillary is displaced from the skin to a second position where the capillary is adjacent the skin while the sampling device remains in contact with the skin; and

drawing the body fluid from the incision into the capillary via capillary action.

19. (Previously Presented): The method of claim 14, further comprising said testing includes analyzing the body fluid with a test strip disposed at an end of the sampling device proximal the skin.

20. (Previously Presented): The method of claim 14, further comprising wherein the non-digit body part is an earlobe or a limb.

21. (Previously Presented): A sampling module comprising:

a module body portion having a sampling site adjacent a lancet exit port where the sharpened distal tip of the lancet exits a distal end of the module body portion that includes a sample cavity in a distal end surface of the module body portion;

a lancet comprising a sharpened distal tip and shaft portion which is slidably disposed within the module body portion and extendable from the lancet exit port; and

a sample reservoir in fluid communication with a sample cavity of the module body portion.

22. (Previously Presented): The sampling module of claim 21 wherein a transverse dimension of the sampling cavity is about 2 to about 5 times a transverse dimension of the lancet shaft portion and wherein a sample flow channel is disposed between and in fluid communication with the sample reservoir and the sample cavity.

23. (Previously Presented): The sampling module of claim 21 wherein the module body portion is configured to be mechanically registered and secured adjacent a lancet driver.

24. (Previously Presented): A tissue penetrating system, comprising:

a penetrating member driver;

a cartridge with a distal port and a proximal port and coupled to the penetrating member driver;

an analyte detecting member coupled to a sample chamber, the analyte detecting member being configured to determine a concentration of an analyte in a body fluid using a sample of a body fluid disposed in the sample chamber;

a penetrating member with a sharpened distal tip and shaft portion that is slidably disposed within the cartridge, wherein a tip of the penetrating member is configured to extend through the opening of the sample chamber; and

a user interface configured to relay at least one of, skin penetrating performance or a skin penetrating setting.

25. (Previously Presented): The tissue penetrating system of claim 24, wherein the sample is less than 1 μL of the body fluid.

26. (Previously Presented): A tissue penetrating system, comprising:

a penetrating member driver;

a cartridge with a distal port and a proximal port and coupled to the penetrating member driver;

an analyte detecting member coupled to a sample chamber, the analyte detecting member being configured to determine a concentration of an analyte in a body fluid using a sample of a body fluid disposed in the sample chamber;

a penetrating member with a sharpened distal tip and shaft portion that is slidably disposed within the cartridge, wherein a tip of the penetrating member is configured to extend through the opening of the sample chamber; and

a human interface providing at least one output.

27. (Previously Presented): The tissue penetrating system of claim 26, wherein the sample is less than 1 μL of the body fluid.

28. (Previously Presented): The system of claim 26, wherein the at least one output is selected from, a penetration event of a penetrating member, number of penetrating members remaining, time of day, alarm, penetrating member trajectory waveform profile information, force for last penetration event, the last penetration event, how or low battery status, analyte status, time to change cassette status, jamming malfunction, and system status.

29. (Previously Presented): The system of claim 26, wherein the human interface is selected from an LED, an LED digital display, an LCD display, a sound generator, a buzzer, and a vibrating device.

30. (Previously Presented): The system of claim 26, wherein the housing is selected from at least one of, a telephone, a watch, a PDA, electronic device, medical device, point of care device and a decentralized diagnostic device.

31. (Previously Presented): The system of claim 26, further comprising: an input device coupled to the housing, the input device selected from one or more pushbuttons, a touch pad independent of the display device, or a touch sensitive screen on a visual display.

32. (Previously Presented): A skin penetrating system, comprising:

a housing member;

a penetrating member positioned in the housing member, and

an analyte detecting member coupled to a sample chamber, the analyte detecting member being configured to determine a concentration of an analyte in a body fluid using a sample of a body fluid disposed in the sample chamber, wherein a tip of the penetrating member is configured to extend through an opening of the sample chamber.

33. (Previously Presented): The skin penetrating system of claim 32, wherein the sample is less than 1 μL of the body fluid.

34. (Previously Presented): The system of claim 32, further comprising:

a tissue stabilizer device coupled to the housing.

35. (Previously Presented): The system of claim 34, wherein the tissue stabilizer device is configured to enhance fluid flow from a target tissue.

36. (Previously Presented): The system of claim 34, wherein the tissue stabilizer device creates a stretching of a skin surface.

37. (Previously Presented): The system of claim 34, wherein the tissue stabilizer device is configured to apply a force to a target tissue and cause the target tissue to press in an inward direction relative to the housing member.

38. (Previously Presented): The system of claim 34, wherein the tissue stabilizing member applies a stimulation to a target tissue.

39. (Previously Presented): The system of claim 32, wherein each penetrating member is an elongated member without molded attachments.

40. (Previously Presented): The system of claim 32, further comprising:

a support structure for receiving the penetrating members.

41. (Previously Presented): A tissue penetrating system, comprising:

a penetrating member driver;

a cartridge with a distal port and a proximal port and coupled to the penetrating member driver;

an analyte detecting member coupled to a sample chamber, the analyte detecting member being configured to determine a concentration of an analyte in a body fluid using a sample of a body fluid disposed in the sample chamber; and

a penetrating member with a sharpened distal tip and shaft portion that is slidably disposed within the cartridge, wherein a tip of the penetrating member is configured to extend through the opening of the sample chamber.

42. (Previously Presented): The tissue penetrating system of claim 41, wherein the sample is less than 1 μL of the body fluid.

43. (Previously Presented): A method of penetrating a target tissue, comprising:

providing a tissue penetrating system with a penetrating member and an analyte detecting member coupled to a sample chamber,;

advancing a penetrating member through the target tissue;

withdrawing the penetrating member from the target tissue.

receiving a body fluid in the sample chamber.

44. (Previously Presented): The method of claim 43, wherein no more than 1 μL of the body fluid is received in the sample chamber.

45. (Previously Presented): A body fluid sampling system for use on a tissue site, the system comprising:

a drive force generator;

a penetrating member operatively coupled to said force generator, said force generator moving said member along a path out of a housing having a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site;

wherein said penetrating member is an elongate member without a molded attachment;

a coupler on said force generator configured to engage at least a portion of said elongate portion of the penetrating member and drive said member along a path into a tissue site and withdrawn from a tissue site;

an analyte detecting member positioned to receive fluid from a wound created by said penetrating member, said detection member configured to determine a concentration of an analyte in the fluid using a sample of less than 1 mL of the fluid; and

a user interface configured to relay at least one of, penetrating member performance or a penetrating member setting.

46. (Previously Presented): A body fluid sampling system for use on a tissue site, the system comprising:

a drive force generator;

a penetrating member operatively coupled to said force generator, said force generator moving said member along a path out of a housing having a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site;

wherein said penetrating member is an elongate member without a molded attachment; a coupler on said force generator configured to engage at least a portion of said elongate portion of the penetrating member and drive said member along a path into a tissue site and withdrawn from a tissue site;

an analyte detecting member positioned to receive fluid from a wound created by said penetrating member, said detection member configured to determine a concentration of an analyte in the fluid using a sample of less than 1 mL of the fluid; and

a human interface providing at least one output.

47. (Previously Presented): A body fluid sampling system for use on a tissue site, the system comprising:

a drive force generator;;

a penetrating member operatively coupled to said force generator, said force generator moving said member along a path out of a housing having said a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site;

a skin stabilizer device suitable for stretching a surface of a tissue site, said skin stabilizer at least partially surrounding the penetrating member exit;

an analyte detecting member positioned to receive fluid from a wound created by said penetrating member, said detection member configured to determine a concentration of an analyte in the fluid using a sample of less than 1 mL of the fluid; and

a user interface configured to relay at least one of, penetrating member performance or a penetrating member setting.

48. (Previously Presented): A body fluid sampling system for use on a tissue site, the system comprising:

a drive force generator;;

a penetrating member operatively coupled to said force generator, said force generator moving said member along a path out of a housing having said a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site;

a skin stabilizer device suitable for stretching a surface of a tissue site, said skin stabilizer at least partially surrounding the penetrating member exit;

an analyte detecting member positioned to receive fluid from a wound created by said penetrating member, said detection member configured to determine a concentration of an analyte in the fluid using a sample of less than 1 mL of the fluid; and

a human interface providing at least one output.

49. (Previously Presented): A body fluid sampling system for use on a tissue site, the system comprising:

a drive force generator;

a penetrating member operatively coupled to said force generator, said force generator moving said member along a path out of a housing having said a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site;

an analyte detecting member positioned to receive fluid from a wound created by said penetrating member, said detection member configured to determine a concentration of an analyte in the fluid using a sample of less than 1 mL of the fluid; and

a user interface configured to relay at least one of, penetrating member performance or a penetrating member setting..

50. (Previously Presented): A body fluid sampling system for use on a tissue site, the system comprising:

a drive force generator;

a penetrating member operatively coupled to said force generator, said force generator moving said member along a path out of a housing having said a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site;

an analyte detecting member positioned to receive fluid from a wound created by said penetrating member, said detection member configured to determine a concentration of an analyte in the fluid using a sample of less than 1 mL of the fluid; and

a human interface providing at least one output.

51. (Previously Presented): A body fluid sampling system for use on a tissue site, the system comprising:

a drive force generator;

a penetrating member operatively coupled to said force generator, said force generator moving said member along a path out of a housing having a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site;

wherein said penetrating member is an elongate member without a molded attachment.

a coupler on said force generator configured to engage at least a portion of said elongate portion of the penetrating member and drive said member along a path into a tissue site and withdrawn from a tissue site;

a skin stabilizing member associated with said housing and positioned to at least partially surround an impact location of the penetrating member on the tissue site;

a user interface configured to relay at least one of, penetrating member performance or a penetrating member setting.

52. (Previously Presented): A body fluid sampling system for use on a tissue site, the system comprising:

a drive force generator;

a penetrating member operatively coupled to said force generator, said force generator moving said member along a path out of a housing having a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site;

wherein said penetrating member is an elongate member without a molded attachment.

a coupler on said force generator configured to engage at least a portion of said elongate portion of the penetrating member and drive said member along a path into a tissue site and withdrawn from a tissue site;

a skin stabilizing member associated with said housing and positioned to at least partially surround an impact location of the penetrating member on the tissue site; and

a human interface providing at least one output.

53. (Previously Presented): A body fluid sampling system for use on a tissue site, the system comprising:

a drive force generator;

a penetrating member operatively coupled to said force generator, said force generator moving said member along a path out of a housing having said a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site;

a skin stabilizing member associated with said housing and positioned to at least partially surround an impact location of the penetrating member on the tissue site;

a user interface configured to relay at least one of, penetrating member performance or a penetrating member setting.

54. (Previously Presented): A body fluid sampling system for use on a tissue site, the system comprising:

a drive force generator;

a penetrating member operatively coupled to said force generator, said force generator moving said member along a path out of a housing having said a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site;

a skin stabilizing member associated with said housing and positioned to at least partially surround an impact location of the penetrating member on the tissue site; and

a human interface providing at least one output.

55. (Previously Presented): A body fluid sampling system for use on a tissue site, the system comprising:

a drive force generator;

a penetrating member operatively coupled to said force generator, said force generator moving said member along a path out of a housing having a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site;

an analyte detection member positioned to receive fluid from a wound created by said penetrating member, said detection member configured to determine a concentration of an analyte in the fluid using a sample of less than 1 mL of the fluid;

a skin stabilizing member associated with said housing and positioned to at least partially surround an impact location of the penetrating member on the tissue site;

a user interface configured to relay at least one of, penetrating member performance or a penetrating member setting.

56. (Previously Presented): A body fluid sampling system for use on a tissue site, the system comprising:

a drive force generator;

a penetrating member operatively coupled to said force generator, said force generator moving said member along a path out of a housing having a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site;

an analyte detection member positioned to receive fluid from a wound created by said penetrating member, said detection member configured to determine a concentration of an analyte in the fluid using a sample of less than 1 mL of the fluid;

a skin stabilizing member associated with said housing and positioned to at least partially surround an impact location of the penetrating member on the tissue site; and

a human interface providing at least one output.

57. (Previously Presented): A body fluid sampling system for use on a tissue site, the system comprising:

a drive force generator;

a penetrating member operatively coupled to said force generator, said force generator moving said member along a path out of a housing having a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site;

wherein said penetrating member is an elongate member without a molded attachment;

a coupler on said force generator configured to engage at least a portion of said elongate portion of the penetrating member and drive said member along a path into a tissue site and withdrawn from a tissue site;

an analyte detecting member positioned to receive fluid from a wound created by said penetrating member, said detection member configured to determine a concentration of an analyte in the fluid using a sample of less than 1 mL of the fluid.

58. (Previously Presented): A method of obtaining a sample of capillary whole blood from a target tissue, comprising

providing a penetrating system that includes a tissue stabilizing member;

applying skin stimulation to a skin surface site with the tissue stabilizing member;

introducing a penetrating member through the skin surface site to form an incision; and

collecting blood from the incision in the penetrating system.

59. (Previously Presented): The method of claim 58, wherein the skin stimulation increases blood circulation at the skin surface.

60. (Previously Presented): A tissue penetrating device, comprising:

a housing;

at least one penetrating member a penetrating member driver coupled to the at least one penetrating member;

a tissue stabilizer member coupled to the housing; and

a human interface providing at least one output.

61. (Previously Presented): The system of claim 60, wherein the at least one output is selected from, a penetration event of a penetrating member, number of penetrating members remaining, time of day, alarm, penetrating member trajectory waveform profile information, force for last penetration event, the last penetration event, how or low battery status, analyte status, time to change cassette status, jamming malfunction, and system status.

62. (Previously Presented): The system of claim 60, wherein the human interface is selected from an LED, an LED digital display, an LCD display, a sound generator, a buzzer, and a vibrating device.

63. (Previously Presented): The system of claim 60, wherein the housing is selected from at least one of, a telephone, a watch, a PDA, electronic device, medical device, point of care device and a decentralized diagnostic device.

64. (Previously Presented): The system of claim 60, further comprising:

an input device coupled to the housing, the input device selected from one or more pushbuttons, a touch pad independent of the display device, or a touch sensitive screen on a visual display.

65. (Previously Presented): The system of claim 60, further comprising:

a data exchange device for coupling the tissue penetrating system to support equipment.

66. (Previously Presented): A body fluid sampling system for use on a tissue site, the system comprising:

a drive force generator;

a penetrating member operatively coupled to said force generator, said force generator moving said member along a path out of a housing having a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site;

wherein said penetrating member is an elongate member without a molded attachment.

a coupler on said force generator configured to engage at least a portion of said elongate portion of the penetrating member and drive said member along a path into a tissue site and withdrawn from a tissue site;

a tissue stabilizing member associated with said housing and positioned to at least partially surround an impact location of the penetrating member on the tissue site

67. (Previously Presented): A body fluid sampling system for use on a tissue site, the system comprising:

a drive force generator;

a penetrating member operatively coupled to said force generator, said force generator moving said member along a path out of a housing having a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site;

an analyte detection member positioned to receive fluid from a wound created by said penetrating member, said detection member configured to determine a concentration of an analyte in the fluid using a sample of less than 1 mL of the fluid;

a tissue stabilizing member associated with said housing and positioned to at least partially surround an impact location of the penetrating member on the tissue site.

68. (Previously Presented): A method comprising:

providing a penetrating member driver;

installing a visual display on said penetrating member driver where said display when coupled to a processor, relays penetrating member information selected from: lancing performance or lancing setting.

69. (Previously Presented): A method comprising:

providing a lancet driver;

installing a visual display on said lancet driver where said display when coupled to a processor, relays lancet information selected from: lancing performance or lancing setting.

70. (Previously Presented): A skin penetrating system, comprising:

a housing member;

a penetrating members positioned in the housing member, and

a tissue stabilizing device coupled to the housing member.

71. (Previously Presented): A skin penetrating system, comprising:

a housing member;

a penetrating member positioned in the housing member, and

a tissue pressure applicator coupled to the housing member.

72. (Previously Presented): A method for sampling body fluids from a patient, the method comprising:

using a human interface on a lancet driver to communicate information to the patient;

actuating said lancet driver to drive a lancet into the patient in a manner sufficient to obtain said body fluid sample.

73. (Previously Presented): The method of claim 72 wherein said human interface is electrically powered.

74. (Previously Presented): The method of claim 72 wherein said human interface is dynamically changable.

75. (Previously Presented): The method of claim 72 wherein said using of the human interface alerts the patient to obtain a body fluid sample.

76. (Previously Presented): The method of claim 72 wherein said human interface alerts said patient via a video indicator.

77. (Previously Presented): The system of claim 71, further comprising: a user interface processor coupled to the user interface.

78. (New): A device for determining the concentration of an analyte in a physiological sample, said device comprising:

(a) a housing having an aperture;

(b) a lancing element having a lancet held therein disposed within said housing;

(c) means for activating said lancing element to displace said lancet through said aperture to provide an incision in an area of skin to provide physiological sample at the surface of said incised area of skin; and

(d) means for determining whether a sufficient amount of said physiological sample is present at the surface of said incised area of skin for analyte concentration determination.

79. (New): The device according to claim 78, further comprising at least one tester stored within said housing.

80. (New): The device according to claim 79, further comprising a tester movement element configured to move said at least one tester in contact with said sufficient amount of sample through said aperture.

81. (New): The device according to claim 80, wherein said tester movement element is actuated manually.

82. (New): The device according to claim 80, wherein said tester movement element is actuated when a sufficient amount of said physiological sample is determined to be present at said area of skin.

83. (New): The device according to claim 78, further comprising a physiological sample promoting element configured to increase the amount of said physiological sample at said surface of said incised area of skin.

84. (New): The device according to claim 78, wherein said device is photometric.

85. (New): The device according to claim 78, further comprising means for determining the concentration of an analyte in said physiological sample.